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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

KRASS, FREDERICK F

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1614

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/663,352
Filing Date: September 15, 2003
Appellant(s): TSENG ET AL.

Robert C. Nabinger
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 24, 2006 appealing from the
Office action mailed 06/16/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

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The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

1) 5,021,053

Barclay et al.

6-1991

2) 4,701,404

Iijima et al

10-1987

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 45-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Barclay et al (USP 5,021,053).

The prior art discloses osmotic delivery devices which are matrices comprising an outer layer made from a water-insoluble polymer, e.g., "lightly crosslinked polystyrene derivatives", *a.k.a.* styrene/rubber polymers, which are also "polystyrene derivatives" as required by instant claim 52 (see col. 9, lines 27-29, and lines 51 and 52), and inner layers comprising a hydrogel and a drug layer, where the inner layers comprise a water-soluble polymer, e.g. polyethyleneoxide (col. 11, lines 50-54 and 62). The rate of release of the drug is measured by providing a color contrast between the drug and hydrogel layers: see the passage bridging col. 7, line 52 to col. 8, line 24.

Working example 1 (col. 15) discloses an osmotic device containing the drug nyastain, which is yellow in color (col. 15, line 34) and water-soluble (col. 19, lines 47-49). Working example 2 (col. 16) discloses a similar device containing the antimicrobial agent chlorhexidine diacetate, which is white in color and similarly water-soluble. Since these drugs are colored, water-soluble, and leach from the delivery device upon repeated contact with water as the patient sucks and/or chews on the device (col. 11, lines 51-53), they are "water-leachable colorants that leach from the matrix when the matrix is exposed to water to provide a change in color" as required by the instant claims. When the drug is chlorhexidine, the matrix "additionally comprises" an

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antimicrobial agent and is “adapted to leach colorant corresponding with the depletion of said antimicrobial agent” as required by instant claims 48 and 49. Moreover, in monitoring the diminishment in the amount of drug left in the device as it is released therefrom, one is monitoring “wear” of the drug-containing layer as required by instant claim 50.

Instant claim 45 recites a color-changing matrix “comprising” a layer “including” a “mixture” of water-insoluble, water-soluble polymer and a water-leachable colorant. There is nothing in the instant specification that requires “a layer” to comprise a single structure. As the term “layer” is typically used in the laminate art, it is inclusive of single layers which themselves further “include” combinations of multiple sublayers. See for example the abstract of USP 4,701,404, which describes an individual layer (“each of said layers”) which is “composed of a plurality of sub-layers”.¹

Similarly, nothing in the instant specification requires that the water-insoluble polymer, water-soluble polymer, and water-leachable colorant be disposed in the same sublayer. A mixture of separate sublayers, each containing one of the polymers in question, forms a larger “layer” which contains the sublayers as a “mixture”. Note also that the instant claim uses the open-ended term “comprising”, which permits the inclusion of additional layers.

Moreover, although mixtures as claimed are implicitly disclosed, the term “mixture” does not appear to be explicitly used, and certainly is never defined, anywhere

¹ The reference was first cited in the final rejection dated 06/16/2005, where it was used for factual verification. It was not substantively part of the rejection, and Applicant did not dispute its use for former purpose.

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in the instant specification. Lacking such a definition, it is appropriate to interpret that term as broadly as is reasonable and to look to an extrinsic source for guidance.

Webster's Ninth New Collegiate Dictionary defines the term "mixture" as:

1(a) : the act, the process, or an instance of mixing **(b1)**: the state of being mixed **(b2)**: the relative proportions of constituents; *specif.* the proportion of fuel to air produced in a carburetor **2**: a product of mixing: COMBINATION as **a**: a portion of matter consisting of two or more components in varying proportions that retain their own properties **b**: a fabric woven of variously colored threads **c**. a combination of several different kinds. (Emphasis original).

Thus, a mixture can contain separate components in separate physical locations, as in a fabric made of various colored threads. The instant claims never require a homogenous mixture. Thus, in the same way, the multilayer structures of Barclay et al form "mixtures" of water-insoluble and water soluble polymers, even though they are not homogeneously combined in the same sublayer. Indeed, this interpretation is entirely consistent with the teachings of the specification, which disclose as preferred embodiments matrices comprising two separate layers, joined together. See for example the passage bridging p. 4, line 27 to p. 5, line 5; p. 6, lines 1-13; and page 18, lines 10 et seq.

(10) Response to Argument

Appellant argues that the term "mixture" has been interpreted incorrectly by the examiner, since definition 2(b) in the Webster's dictionary definition relates to fabrics made of variously colored threads, and not chemical compositions. This argument is not

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on point. The “mixture” at issue here is a physical mixture of two sublayers; a fabric analogy is entirely appropriate.

Appellant further argues that “layer” has been “defined” as meaning a section of the template that has a particular composition, as stated at p. 4, lines 27-30 of the specification, and thus is distinguished over the prior art.

The examiner does not agree.

The specification states at p. 4, lines 11-13 that *the matrix* is a flat template, *i.e.* one single overall layer.

The section referenced by Appellant following this general definition is merely a description (not a definition) of a two-layer embodiment of same:

In other preferred embodiments, the matrix includes two layers, joined together. By “two layers”, it is meant that one section of the template has a different composition than a second section. The first outer layer includes a support resin or a water-soluble polymer, and an antimicrobial agent; the second inner layer includes the support resin. Significantly, the first layer can include a large quantity of anti-microbial agent because the layer includes less (or none) of the support resin, yet the layer is stable because the co-extruded second layer provides the necessary support. The second layer may also include, optionally, some water-soluble polymer and/or anti-microbial agent. (Emphasis added).

Thus, the matrix may have individual sublayers, which may or may not differ in composition, but the matrix is still one overall layer. This interpretation is not precluded by the section referenced by Appellant, and is wholly consistent with the state of the prior art as illustrated by USP 4,701,404, discussed supra. It is also supported by the specification's further description at the first paragraph of p. 18:

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An alternative two-layer embodiment has an outer layer consisting only of the support resin and the anti-microbial agent. The preferred anti-microbial agent, chlorhexidine digluconate, is water-soluble, although not to the same degree as the water-soluble polyethylene oxide. Because the outer layer includes a high quantity of the anti-microbial agent, enough of the agent can dissolve out of the matrix to provide a sufficient dosage of the agent without the assistance of a water-soluble polymer.

This describes a prior art sublayer. That sublayer can then be combined with another sublayer to provide a matrix having one overall layer (while comprising two sublayers), analogous to those described by USP 4,701,404. Thus, contrary to Appellant's assertions, when comparing Barclay to claim 45, interpretation of the term "layer" to encompass adjoining outer and inner sections having different compositions is not incorrect.

(11) Related Proceeding(s) Appendix

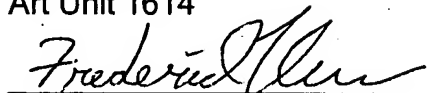
No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

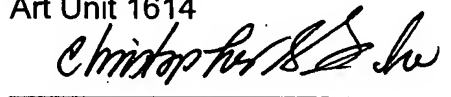
Frederick Krass
Primary Examiner
Art Unit 1614



Conferees:

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

Christopher Low
Supervisory Patent Examiner
Art Unit 1614



Michael Hartley
Supervisory Patent Examiner
Art Unit 1618

